Sections Included in this Document and Document History

1. Purpose

The [Name (i.e. District Office or Laboratory)] conducts systematic internal audits to monitor and determine compliance with the requirements of the quality system and standards. The [Name (i.e. Laboratory Branches)] perform [Time Interval (e.g. quarterly] performance audits to evaluate the technical activities of employees and product produced by those employees. The quality system needs to evolve or continually improve to fulfill its purpose. This procedure establishes the method by which internal audits and performance audits are performed within the [Name].

2. Scope

This procedure applies to [Name] activities that directly affect the quality of work products.

Internal quality system audits are performed on a predetermined schedule and as otherwise directed by management. Performance audits are performed [Time Interval (e.g. quarterly)] by the [Name (i.e. Laboratory Branches)]. Summary reports of audits are maintained by the Quality Management System Manager.

3. Responsibilities

A. [Third Level Manager]:

- ensures information and access is provided to auditors, and
- completes corrective action.

B. [Second Level Manager]:

- informs staff of audit schedule and
- ensures corrective action is taken on findings and follow-up actions.

C. [First Level Manager]:

- establishes and maintains organizational, operational and quality policies; and
- provides for the personnel and resources to ensure that activities used are capable of meeting the needs of the customers.

D. Quality Management System Manager (QMS):

- provides any forms or checklists,
- acts or designates lead auditor,
- coordinates the audit and ensures that auditors have the correct training and guidance for their work,
- monitors audit activities, assembles summary report and initiates corrective action,
- monitors timely resolution of audit findings,
- maintains summary reports, and
- coordinates regional performance audits.

E. Auditor:

- reviews background documentation,
- performs audit in accordance with audit schedule and checklist, and
- collects objective evidence to support findings.

4. Background

None.

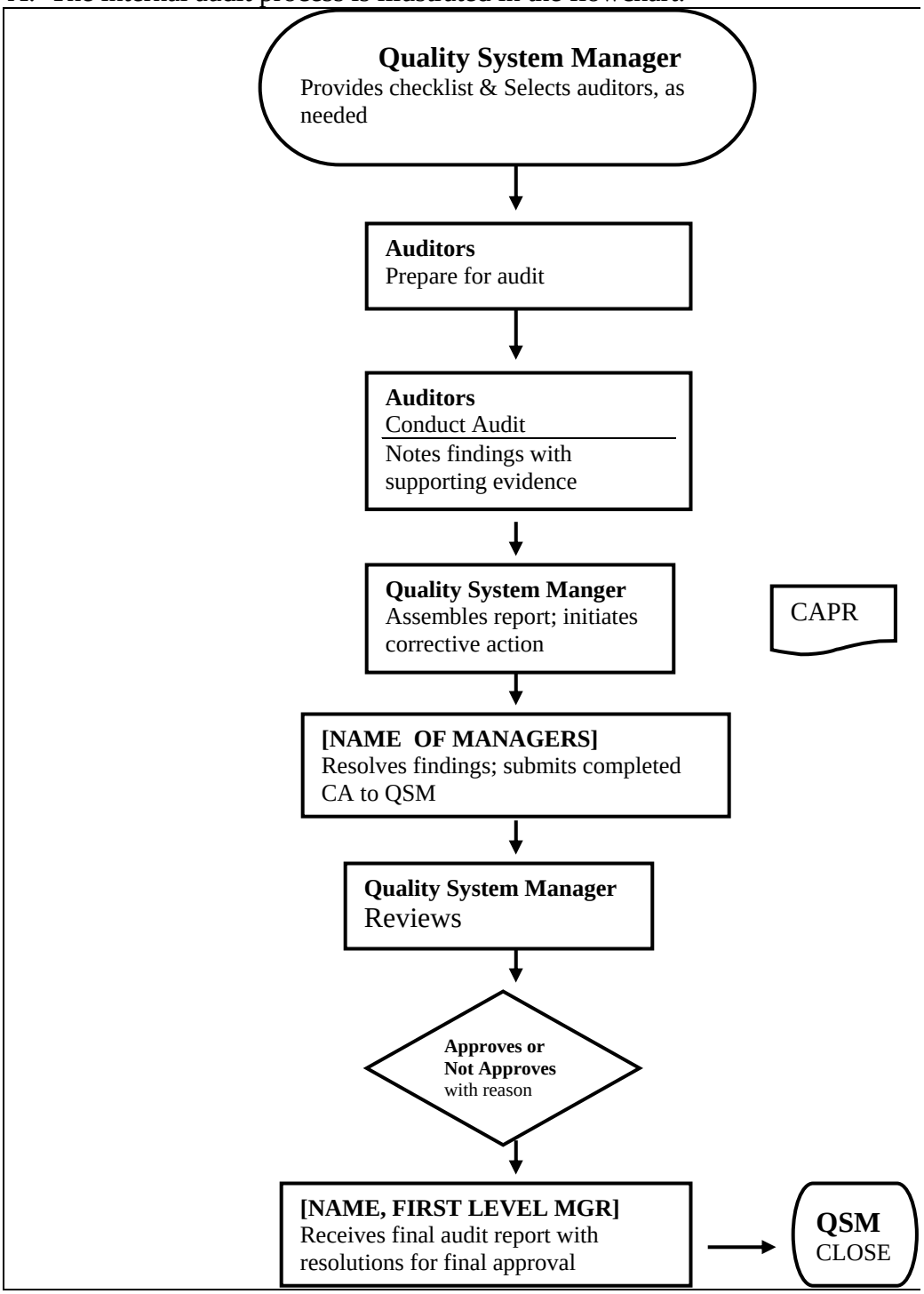
5. References

A. EAL-G3, Internal Audits and Management Review for Laboratories
B. ISO 19011:2002, Guidelines for Quality and/or Environmental Management Systems Auditing.

6. Procedure

6.1 Internal Audits Flowchart

A. The internal audit process is illustrated in the flowchart.



6.2 Internal Audit Process

A. Internal system audits are planned and scheduled by the Quality Management System Manager. The review activity and ISO 17025 internal audit schedules are defined in Attachment A.

B. The areas to be audited will be detailed out in this schedule. These areas include:

- ISO requirements checklist review;
- methods and procedures;
- review procedures;
- staff and record keeping of training;
- equipment and functional verification and preventive maintenance charts;
- proficiency surveys;
- quality control (QC) and QC charts;
- workload, sample and data handling processes;
- records and reports (work products);
- standards, organisms, certified reference materials;
- housekeeping;
- chemical storage;
- hazardous waste; and
- laboratory environment.

C. Audits will be carried out by personnel who are independent of the area they are examining. Personnel conducting audits are trained and qualified based upon completion of one or more of the following criteria:

- previous demonstration of performing audits (e.g. FDA inspections, ORA audits);
- documented training conducted by laboratory QMS Manager; and
- successful completion of a recognized auditing course.

D. The QMS Manager may direct examinations of single aspects of the Quality Management System (e.g. laboratory reports).

E. Checklists to be used and previous audits reports, corrective actions and

audit checklists are provided to the auditors by the QMS Manager to the designated lead auditor for distribution and review.

F. If an audit team or external auditor is utilized, the team or auditor will on the day of audit begin by meeting with the [Name] and [Name] responsible for the functional areas and sections to be audited. During this meeting, the lead auditor will introduce the audit team, outline the plan of action and obtain the names of the section personnel who should be contacted to assist the auditors in each functional area.

G. Auditors conduct the audit in accordance with the schedule and document audit findings. Auditors receive information through several sources:

- interviews with personnel,
- examination of documentation,
- observation of activities and conditions,
- review of quality and technical records, and
- use of checklists.

H. In order to assess all areas of the audit, auditors may select a violative case and follow its progress from beginning to end examining all aspects of the quality system relating to it.

I. Upon completion of the audit, the lead auditor will compile the findings and provide the section representatives with a preliminary report. This preliminary report is a synopsis of the findings and provides section personnel with an opportunity to voice any objections. If valid objections are raised, the audit team should adjust their findings accordingly.

J. The QMS Manager assimilates all data from the audit and prepares an audit summary report. The audit report, corrective actions and follow-up activities are discussed [Frequency (e.g. weekly)] during management meetings.

K. A Corrective Action form is initiated for audit findings by the QMS Manager for the Branch Directors or designee to complete. The QMS Manager will track and monitor the progress of corrections, provide assistance and direction as needed. Corrective action is undertaken by the responsible [Name] and [Name] and resolutions submitted to the QMS Manager within 30 days.

L. A resolution report of corrective actions taken and follow-up activities is prepared by the QMS Manager through the [Name] to the [Name] and staff.

M. In the event, the audit identifies a problem associated with incorrect procedures, invalid action or invalid data, immediate corrective action will be taken. The QMS Manager will notify the [Name] to determine the most efficient method of notifying the client (i.e. by telephone, email, fax or letter). This notification will be documented. Corrected reports will be issued.

6.3 Performance Audits

A. Performance audits are performed quarterly by each [Name (i.e. Laboratory Branch)] and coordinated by the QMS Manager. Corrective action is performed on noted discrepancies. Performance audits are included as part of the internal audit.

B. Completed review forms are returned to the [Name] for review.

C. Forms and memorandums are submitted to the QMS Manager for review and filing. A Corrective Action form is initiated for discrepancies noted by the QMS Manager for the Branch Director or designee to complete. Corrective action is undertaken and resolutions submitted to the QMS Manager within 30 days.

D. A [Time Interval (e.g. bi-annual)] summary report is submitted to the regional office by the QMS Manager through the [Name].

E. Performance Audits

1. Worksheet Review

a. An Analyst Worksheet Quality Assurance (QA) Review form is completed by the [Name] for at least [Number] of Class 3 worksheets [Time Interval (e.g. quarterly].

b. An Analyst Worksheet QA Review form is completed by the [Name] for at least [Number] Class 1 and Class 2 worksheets [Time Interval (e.g. quarterly)].

c. An Analyst Worksheet QA Review form is completed by the Supervisor at the rate of one worksheet for each analyst [Time Interval (e.g. quarterly)].

d. Field Accomplishment and Compliance Tracking System (FACTS) information is checked for accuracy, completeness and agreement with hardcopy worksheet.

e. On-the-spot corrective action is annotated on the form.

2. Sample Accountability Review

a. A Sample Accountability QA Review form is completed for [Number] assigned samples, [Number] unassigned samples and [Number] closed samples.

b. FACTS information is checked for accuracy and completeness.

c. On-the-spot corrective action is annotated on the form.

3. Oral Review (Optional)

a. The QMS Manager schedules through the Compliance Branch Director depending on workload and availability of compliance officers oral reviews quarterly. The goal is to conduct an oral review for each analyst and technician within four years.

b. An Oral Review form, selected analyst worksheets and applicable procedures and programs are distributed to personnel in advance.

c. The analyst or technician verbally answers the questions to the Compliance Officer (CO) with their Supervisor in attendance.

d. The CO evaluates the responses and completes the Oral Review form and returns documentation to the [Name].

e. On-the-spot corrective action is annotated on the form.

4. On-Site Review

a. An On-Site Review form is completed for each analyst or technician annually.

b. On-the-spot corrective action is annotated on the form.

5. Laboratory Controls QA Review

   a. A Laboratory Controls QA Review form is completed.

7. Definitions

Audit - An audit is a planned and documented investigative evaluation of an item or process to determine the adequacy of and compliance with planned arrangements and whether these arrangements are implemented effectively and are doable to achieve objectives.

Audit summary report – An Audit Summary Report is a summary of the audit scope and findings, as illustrated by Attachment A.

Corrective action request (CAR) – A Corrective Action Report is a request to initiate corrective action.

Fitness-for-use criteria – These criteria are quality elements needed for purposeful work. Work requests or compliance programs directing a piece of work or general guidance documents, such as the *Laboratory Manual*, the *Quality Management System Manual*, pertinent laboratory procedures and work instructions, contain quality elements.

Monitor – To monitor is to observe and record activity to measure compliance with a standard of performance, routine and ongoing collection of data about the indicator.

Non-conformity – A non-conformity is non-fulfillment of a specified or implied requirement of the quality management system or of a quality work product.

Objective evidence – Objective evidence is information, which can be proven true, based on facts obtained through observation, measurement, test, or other means.

Observation – An observation is objective evidence that creates concern that may indicate future problems.

On-the-spot corrective action - This is an immediate step taken to correct or resolve a non-conformity.

Performance audit – a performance audit is an assessment of the technical activities of personnel and are categorized as a quantitative appraisal of

quality.

Requirement – A requirement is a declared, implied or routine need or expectation.

System audit – A system audit is an on-site assessment of the laboratory's quality management system and referred to as a qualitative appraisal of quality.

8. Records

Audit Summary Report
Audit Resolution Report
Corrective Action and Problem Reports
Performance Review forms

9. Supporting Documents

[Name]-Corrective Action Procedure

10. Attachments

Attachment A: Examples of Audit Schedules
Attachment B: Audit Summary Report
Attachment C: Resolution of Audit Findings

Document History					
Version No.	**Status** (I, R, C)	**Date Approved**	**Location of Change History**	**Name & Title**	
				Author	**Approving Official**

Approving Official's signature: _____ Date: _____

EXAMPLE 1:

Review Activity	Reviewer	Review Forms	Schedule/Required Amount
Lab Analyst Worksheets	Supervisors Laboratory Director Name	Analyst Worksheet QA Review	Quarterly – Minimum of 2 per analyst per year Quarterly – 9 Class 1 and 2 per quarter Quarterly – 7 Class 3 per quarter
Sample Accountability	Name	Sample Accountability QA Review	Quarterly – 15 per quarter randomly selected from FACTS electronic records: 10 Active – 5 Assigned In Process or In-Process and 5 Unassigned 5 Completed
Oral Review	Name	Oral QA Review	Depending on workload and availability of COs 1 review per analyst or technician every 4 years
Lab On-Site Review	Supervisors	On-Site QA Review	1 review per analyst per year
Laboratory Controls	Name	Maintenance & Calibration of Equipment Standards, Reagents, Media & Miscellaneous Environmental Controls	Quarterly – 5 instruments per quarter Quarterly – 6 per quarter Quarterly – 7 per quarter
Internal System Audit Report	QMS; assigned auditors	Audit Summary Report (See schedule)	Annually (Report-2nd Quarter)
Management Review Report	District Director; QMS	Management Review Memo	Annually (Report-2nd Quarter)

Example 2: Monthly Fiscal Year Schedule

ISO Element No.	**OCT**	**NOV**	**DEC**	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUNE**	**JULY**	**AUG**	**SEP**
4.1, 4.2												
4.3,4.6												
4.4,4.14												
4.8,4.9												
4.10, 4.11												
4.12, 4.13												
5.2, 5.3												
5.4, 5.5												
5.6, 5.8												
5.9,5.10												
COMPLETED												

EXAMPLE 3: Quarterly Fiscal Year Schedule

Element to be Audited	**17025 Reference**	**Activities checked**	**Schedule (To Be Determined by Laboratory)**
Organization	4.1	Organization Charts (up-to-date); responsibilities & job descriptions documented	1st Quarter of Fiscal Year
Quality Management System	4.2	Lab Manual; QMS.8 (up-to-date)	1st Quarter of Fiscal Year
Document Control	4.3	QMS.1; MasterList.mdb	1st Quarter of Fiscal Year
Review of Requests and Contracts	4.4	Work Plan Review	
Purchasing Services and Supplies	4.6	ADM.1; ADM.2; purchasing files	1st Quarter of Fiscal Year
Complaints	4.8	QMS.4; CC1.mdb (up-to-date)	1st, 2nd, 3rd, and 4th Quarters
Control of Non-conforming Testing	4.9	QMS.8	4th Quarter
Corrective Actions	4.10	QMS.3; CAPR1.mdb (up-to-date)	1st, 2nd, 3rd, and 4th Quarters
Preventive Actions	4.11	Action plans (implementation, if any) Instrument Contracts	1st Quarter 4th Quarter
Control of records	4.12	QMS.6 (request records from file room and another home district); QMS.9 (data backups performed)	4th Quarter
Internal Audits	4.13	Performed as scheduled	1st, 2nd, 3rd, and 4th Quarters
Management Review	4.14	QMS.2 (all elements examined)	2nd (if possible) and 4th Quarter
Personnel	5.2	QMS.5; training files; competency charts; on-site reviews performed	1st Quarter 4th Quarter 1st, 2nd, 3rd, and 4th Quarters
Environment	5.3	Environmental records maintained; access control; housekeeping	1st, 2nd, 3rd, and 4th Quarters
Test methods and method validation	5.4	LB.46; validation files; Methods & SOPs current; operator manual listing; Measurement uncertainty	1st Quarter 1st, 2nd, 3rd, and 4th Quarters 4th Quarter 4th Quarter
Equipment	5.5	FV/PM charts *Out of Service* tagged	1st, 2nd, 3rd, and 4th Quarters
Measurement Traceability	5.6	Standard Inventory; Certificates (on file) Storage	4th Quarter
Handling of test items	5.8	Sample custodian room – receipt, retention, storage	1st, 2nd, 3rd, and 4th Quarters
Assuring the quality of test results	5.9	QC charts; proficiency rounds; QA spreadsheet	1st, 2nd, 3rd, and 4th Quarters
Reporting results	5.10	Analyst worksheets	1st, 2nd, 3rd, and 4th Quarters

DATE:

FROM: [Name]

THRU: [Name]

TO: [Name]

SUBJECT: Internal Audit Summary Report

An internal audit was conducted (dates). The main emphasis of this audit is the internal assessment of the quality management system. This assessment determines whether or not the [Name] is operating in accordance with the policies and procedures set out in the quality manual and related documentation.

The following areas were reviewed and findings include:

TITLE: Brief description

TITLE: Brief description

DATE:

FROM: [Name]

THRU: [Name]

TO: [Name]

SUBJECT: Resolution of Audit Findings

1. Title (Brief description of corrective action)

2. Title (Brief description of corrective action)

3. Implementation and effectiveness of corrective actions.

    a. Number of corrective actions determined to be effective
    b. Number and Identification of corrective action assigned for more follow-up